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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,104	04/24/2001	Fritz Magerl	LUD-PT002-PA1083US	6204
3624	7590	09/14/2004	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			CHEVALIER, ALICIA ANN	
			ART UNIT	PAPER NUMBER
			1772	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/701,104

**Applicant(s)**

MAGERL ET AL.

**Examiner**

Alicia Chevalier

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 13 is/are rejected.
- 7) ☒ Claim(s) 11,12,15 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**RESPONSE TO AMENDMENT**

***Request for Continued Examination***

1. The Request for Continued Examination (RCE) under 37 CFR 1.53 (d) filed on May 17, 2004 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1, 3-13, 15 and 19 are pending in the application, claims 2, 14, 16-18 have been cancelled.
3. Amendments to the claims, filed on May 17, 2004, have been entered in the above-identified application.

***WITHDRAWN REJECTIONS***

4. The 35 U.S.C. §112, first paragraph, rejections of claims 1, 3-13 and 15, made of record in paper #12, mailed November 19, 2003, pages 3-4, paragraph #9 have been withdrawn due to Applicant's amendment in the response filed May 17, 2004.

***NEW REJECTIONS***

5. **The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 was amended to recite the limitation "fibers that do not absorb substantial amounts of x-rays" in the amendment filed August 28, 2003. The specification merely recites that the composite consists of either fibers made out of a material with a higher x-ray absorption (*Applicant's specification page 2, line 29 through page 3, line 3*) or consists of carbon fibers and fibers made out of a material with a high x-ray absorption (*Applicant's specification page 3, line 32 through page 4, line 2*). Therefore, there is no support for the limitation "fibers that do not absorb substantial amounts of x-rays" and it is considered new matter. There is only support in the specification for x-ray absorption fibers mixed with carbon fibers.

The new matter should be deleted.

### ***Claim Rejections - 35 USC § 102***

8. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Sicurelli, Jr. et al. (U.S. Patent No. 5,919,044).

Regarding Applicant's claim 9, Sicurelli discloses a component (*post, col. 14, lines 10*) made from a composite of polymer or ceramic material (*reinforced plastics, col. 14, line 11*) having x-ray absorbing reinforcing fibers (*steel or platinum fibers, col. 14, lines 15-18*)

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distributed throughout the composite (*figures 12 and 13*). Applicant gives examples of x-ray absorbing reinforcing fibers such as steel, tantalum, tungsten, gold, platinum etc. (*Applicant's specification page 4, lines 23-30*).

From figures 12 and 13 it can be seen that the x-ray absorbing reinforcing fibers have an orientation tailored to the shape and application of the component, i.e. dental post implant (*col. 7, line 66*), in a defined manner.

Sicarelli does not explicitly teach "an orientation of the x-ray absorbing fibers ... to provide x-ray visibility control for the component." However, it is reasonable to presume that Sicarelli's post, i.e. component, would meet the above limitation because Sicarelli's post is substantially identical in composition and structure to Applicant's disclosed component. MPEP § 2183. The Examiner's basis for this assertion is that Sicarelli's post has the same x-ray absorbing fibers, i.e. steel or platinum, and the fibers have an orientation tailored to the shape and application of the component.

### ***Claim Rejections - 35 USC § 103***

9. Claims 1, 3-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loher et al. (WO 96/19336) in view of Sicarelli.

Loher discloses components made of fiber-reinforced thermoplastic materials used as connecting elements, particularly for use in medical technology for bone screws (*page 1, lines 12-17*).

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Regarding Applicant's claim 1, Loher discloses a composite of polymer or ceramic material (*title*) for the manufacture of components used in biological implants (*bone screws, page 1, lines 12-17*).

The composite comprises fibers (*carbon fibers, page 3, lines 29-30*) that do not absorb substantial amounts of x-rays (*x-ray-transparent, page 9, lines 1-2*) located in a polymer or ceramic material (*PAEK (polyaryl ether ketones), page 3, line 29*).

Loher fails to disclose x-ray absorbing reinforcing fibers distributed within the composite throughout the fibers that do not absorb substantial amounts of x-rays in a defined manner to provide x-ray visibility control for the biological implant components.

Sicurelli discloses a component used as a dental post implant (*col. 14, lines 10*) or for other types of bone implants to reduce resorption bone dissolution due to stress or infection (*col. 11, lines 20-23*).

Sicurelli discloses a component (*post, col. 14, lines 10*) made from a composite of polymer or ceramic material (*reinforced plastics, col. 14, line 11*) having x-ray absorbing reinforcing fibers (*steel or platinum fibers, col. 14, lines 15-18*) distributed throughout the composite (*figures 12 and 13*). Applicant gives examples of x-ray absorbing reinforcing fibers such as steel, tantalum, tungsten, gold, platinum etc. (*Applicant's specification page 4, lines 23-30*).

From figures 12 and 13 it can be seen that the x-ray absorbing reinforcing fibers have an orientation tailored to the shape and application of the component, i.e. dental post implant (*col. 7, line 66*), in a defined manner.

Sicurelli does not explicitly teach “an orientation of the x-ray absorbing fibers ... to provide x-ray visibility control for the component.” However, it is reasonable to presume that Sicurelli’s post, i.e. component, would meet the above limitation because Sicurelli’s post is substantially identical in composition and structure to Applicant’s disclosed component. MPEP § 2183. The Examiner’s basis for this assertion is that Sicurelli’s post has the same x-ray absorbing fibers, i.e. steel or platinum, and the fibers have an orientation tailored to the shape and application of the component.

Loher and Sicurelli are analogous because they both discuss bone implants.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add Sicurelli’s metal x-ray absorbing fibers to Loher’s component in order to bone strength. One of ordinary skill in the art would have been motivated to use metal x-ray absorbing fibers because it helps to reduce resorption bone dissolution due to stress or infection (*Sicurelli col. 11, lines 20-23*).

Regarding Applicant’s claim 3, Loher discloses that the composite is prefabricated as a profiled rod material comprised of thermoplastics with fibers, since the reference discloses that the composite blank has a rod-shape (*page 7, line 14 and figure 1*) and comprises a thermoplastic with carbon fibers (*PAEK (polyaryl ether ketones) reinforced with carbon fibers, page 9, line 16*).

Regarding Applicant’s claim 4, Loher discloses that the composite comprises carbon fiber-reinforced PAEK (poly-aryl-ether ketone) (*PAEK (polyaryl ether ketones) reinforced with carbon fibers, page 9, line 16*).

Regarding Applicant's claim 5, Loher discloses that the carbon fibers are designed as continuous fibers and/or fibers with a length exceeding 3 mm, since the reference discloses that the fibers have length of more than 3 mm (*page 4, lines 16-17*). Sicurelli discloses that the x-ray absorbing fibers are designed as continuous fibers and/or fibers with a length exceeding 3 mm, since the reference discloses that fibers have a standard length of 5/8 inch (*col. 10, lines 56-59*), which is about 15 mm.

Regarding Applicant's claim 6, as seen in figures 1 and 2 of Loher the fibers are enveloped, i.e. embedded, by the matrix material.

Regarding Applicant's claims 7 and 8, Sicurelli discloses that the x-ray absorbing fibers comprise a nonmagnetic material and are selected from the group comprising tantalum, tungsten, gold, and platinum, since the reference disclose the fibers are made of platinum (*col. 14, lines 15-18*).

Regarding Applicant's claim 9, Loher discloses a component made from a composite of polymer or ceramic material with reinforcing fibers distributed throughout the composite (*PAEK (polyaryl ether ketones) reinforced with carbon fibers, page 9, line 16*).

It is noted that Loher fails to disclose x-ray absorbing reinforcing fibers distributed throughout the composite throughout wherein an orientation of the x-ray absorbing reinforcing fibers is tailored to the shape and application of the component in a defined manner to provide x-ray visibility control for the component. However, Sicurelli discloses these limitations as addressed above.

Regarding Applicant's claim 10, Loher discloses the fibers are oriented differently depending on the longitudinally or transverse oriented alignment of the component, since the



reference discloses that the fibers are aligned in locally targeted manner to adjust rigidity (*page 8, lines 25-26*). Also figure 2 shows that the fibers are oriented differently depending on the longitudinally or transverse oriented alignment of the component.

Regarding Applicant's claim 13, Loher discloses a component in the form of a connecting element (*bone screw, page 1, lines 12-17*), where the stiffness of the connecting element can be varied by varying the orientation of fibers from a force application point toward a free end of the component, since the reference discloses that the alignment of the fibers within the structure are locally oriented (*figure 2*) to adjust the rigidity of the target area (*page 8, lines 25-26*).

#### ***Allowable Subject Matter***

10. Claim 11, 12, 15 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***ANSWERS TO APPLICANT'S ARGUMENTS***

11. Applicant's arguments in the response filed May 17, 2004 regarding the previous rejections of record have been considered but are moot since the rejections have been withdrawn.

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***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Chevalier whose telephone number is (571) 272-1490.

The examiner can normally be reached on Monday through Friday from 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alicia Chevalier

8/22/04